IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application

Inventors: David Feygin et al.

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Title: Vascular-Access Simulation System with External End-Effector

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

APPEAL BRIEF UNDER 37 CFR 41.67

Pursuant to 37 CFR 41.67, this brief is filed in support of the appeal in this application.

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REAL PARTY IN INTEREST

The real party of interest in this application is the assignee of this application is Laerdal.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

STATUS OF CLAIMS

Claims 2-3, 7, 9, 11, 13-14, 18, and 20-28 have been canceled and claims 1, 4-6, 8, 10, 12, 15-17, and 19 are pending. Each of the pending claims stand rejected. All of the rejected claims are being appealed.

STATUS OF AMENDMENTS

No amendments have been filed subsequent to the final rejection of the claims.

SUMMARY OF THE CLAIMED SUBJECT MATTER

The application on appeal relates to a simulator for practicing vascular-access procedures, such as inserting a needle and/or catheter into a vein, without the use of a human subject. In the illustrative embodiment, vascular-access simulator (100) includes haptics device (102) and data-processing system (104). *See* FIG. 1.

The term "haptics," as in "haptics device (102)," relates to touch; in particular, the sense of touch. A fundamental function of haptics device (102), and indeed any haptics interface, is to create a means for communication between human users and machines. This "communication" is possible since humans are capable of "mechanically" interfacing with their surroundings due, at least in part, to a sense of touch. Thus, haptics device (102) is the physical interface for performing simulated vascular-access procedures.

Haptics device (102) includes an "end effector" and a "receiver." The end effector (the term is borrowed from robotics) is realized, in the illustrative embodiment, as needle/catheter module (218). The needle/catheter module is physically representative of a needle and catheter. *See* FIGs. 5-7.

In the illustrative embodiment, the receiver is realized as needle-stick module (226). The needle-stick module is disposed within housing (216) and located beneath pseudo skin (220), which is co-extensive with at least a portion of the surface of the housing. To provide a more realistic training experience, the housing is sized and subtly shaped like a portion of a human arm, but is nondescript enough to avoid creating a discontinuity between what is seen and what is felt.

During a simulation exercise, a user inserts needle/catheter module (218) through pseudo-skin (220) into needle-stick module (226) with the housing, thereby simulating the insertion of a needle and catheter into a patient's arm. As discussed further below, needle-stick module (226) provides force feedback to a user.

The needle-stick module provides one linear degree of freedom and two independent rotational degrees of freedom; in particular, pitch and yaw. The linear degree of freedom enables a user to advance needle/catheter module (218) into the housing, mimicking the insertion of a needle/catheter into a patient's arm. The rotational degrees of freedom enable a user to move an engaged needle/catheter module up or down and left or right. This mimics the freedom of movement that a user has during an actual vascular-access

procedure. Sensors located within the haptics device track insertion depth, pitch and yaw. *See* FIGs. 10A-10C and 11A-11D for detailed mechanical depictions of needle-stick module (226).

As a user inserts needle/catheter module (218) into needle-stick module (226), the user senses a variable resistance to the continued advance (insertion) of needle/catheter module (218). The resistance is intended to simulate penetration of the skin, a vein, and harder structures such as ligaments, bones, and the like. The resistance advantageously varies with insertion depth as well as the pitch and yaw of needle/catheter module (226). This mimics an actual vascular access procedure, wherein a needle would encounter different anatomical features as a function of its location within a patient's arm. The amount of force feedback that is applied by needle-stick module (226) is determined by data processing system (104). Specifically, data obtained by the sensors regarding insertion depth, pitch, and yaw is input to an anatomical model operating within the data processing system. *See* FIGs. 8-9 for a figurative illustration of the force-feedback system.

In some embodiments, simulator (100) is capable of sensing the orientation of needle/catheter module (218) about its long (roll) axis. This enables the simulator to determine the orientation of a feature of a needle or catheter, such as a "bevel." This is an important aspect of an actual vascular access technique, since proper bevel orientation reduces a patient's discomfort during needle/catheter insertion.

The independent claims 1 and 12 on appeal are presented below and mapped to the specification by page and line number and to the drawings, as applicable.

Claim 1 recites an apparatus comprising:

> a needle/catheter module, wherein the needle/catheter module comprises:
> a needle;
> a catheter, wherein said catheter receives said needle, and wherein at least one of said needle or said catheter comprise a bevel;
> a sensor, wherein said sensor senses an orientation the bevel; and
> pseudo skin, wherein said pseudo skin comprises an opening for receiving said needle and said catheter.

Needle-catheter module: identified by call out "218," is first referenced in paragraph [0048] and appears extensively elsewhere throughout the specification. *See* detailed discussion at paragraphs [0067] through [0072] and FIGs. 5-7.

Needle: identified by call out "650," is first referenced at paragraph [0067]; *see also* FIG. 6.

Catheter: identified by call out "758," is first referenced at paragraph [0067]; *see also* FIGs. 5 and 7.

Bevel: identified by call out "760," is first referenced at paragraph [0068]; *see also* paragraph [0054], [0072], FIG. 7.

Sensor: (for sensing bevel orientation) identified by call out "538," is first referenced at [0068]; *see also* paragraph [0070], FIGs. 5 and 6.

Pseudo skin: identified by call out "220," is first referenced at paragraph [0048]; *see also* paragraphs [0038], [0050]-[0053], FIGs. 3 and 4A.

Opening: identified by call out "334," is first referenced at paragraph [0051]; *see also* FIGs. 3, 4A, and 4B.

Claim 12 recites an apparatus comprising:

> pseudo skin;
> a force-feedback assembly, wherein said force-feedback assembly is disposed beneath and is at least partially covered by said pseudo skin; and
> an end effector, wherein said end effector passes through said pseudo skin to reversibly couple to said force-feedback assembly, and further wherein said end effector comprises a needle catheter module, wherein said needle-catheter module includes:
> a needle;
> a catheter, wherein said catheter receives said needle, and wherein an end of at least one of said needle or said catheter comprises a bevel; and
> a sensor, wherein said sensor senses an orientation of said bevel.

Pseudo skin: identified by call out "220," is first referenced at paragraph [0048]; *see also* paragraphs [0038], [0050]-[0053], FIGs. 3 and 4A.

Force-feedback assembly: identified by call out "862," is first referenced at paragraph [0073]; *see also* paragraphs [0076]-[0078], [0080], [0087]-[0088], [0092], FIGs. 8 and 9.

End effector: referenced at paragraph [0038]; *see also* paragraph [0048].

Needle-catheter module: identified by call out "218," is first referenced in paragraph [0048] and appears extensively elsewhere throughout the specification. *See* detailed discussion at paragraphs [0067] through [0072] and FIGs. 5-7.

Needle: identified by call out "650," is first referenced at paragraph [0067]; *see also* FIG. 6.

Catheter: identified by call out "758," is first referenced at paragraph [0067]; *see also* FIGs. 5 and 7.

Bevel: identified by call out "760," is first referenced at paragraph [0068]; *see also* paragraph [0054], [0072], FIG7.

Sensor: (for sensing bevel orientation) identified by call out "538," is first referenced at [0068]; *see also* paragraph [0070], FIGs. 5 and 6.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The single ground of rejection for review on appeal is whether claims 1, 4-6, 8, 10, 12, 15-17, and 19 were properly rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 6,470,302 in view of U.S. Pat. No. 5,821,920 and further in view of U.S. Pat. No. 4,850,960.

ARGUMENTS

Claims 1, 4-6, 8, 10, 12, 15-17, and 19 were rejected under 35 USC §103(a) over U.S. Pat. No. 6,470,302 to Cunningham *et al*. (hereinafter "Cunningham") in view of U.S. Pat. No. 5,821,920 to Rosenburg *et al*. (hereinafter "Rosenburg") and further in view of U.S. Pat. No. 4,850,960 to Grayzel (hereinafter "Grayzel"). Apellant traverses.

Claim 1 recites:

> a needle/catheter module, wherein the needle/catheter module comprises:
> a needle;
> a catheter, wherein said catheter receives said needle, and wherein at least one of said needle or said catheter comprise *a bevel*;
> a sensor, wherein said *sensor senses an orientation the bevel*; and
> pseudo skin, wherein said *pseudo skin comprises an opening for receiving said needle and said catheter*. (Emphasis added.)

Cunningham discloses an interface device for interfacing instruments to a vascular-access simulation system. The Cunningham device was available for sale and was supplying the market for vascular access simulators when appellant's claimed device was being developed. The device disclosed in Cunningham was well known to appellant (they were competitors) and, in fact, the Cunningham device was the starting point for appellant's development efforts for a vascular-access simulator. In other words, appellant scrutinized the Cunningham device, identified its many shortcomings, and engineered a competing device that was intended from the start to address the shortcomings of the Cunningham device and provide a vascular access simulator having greater utility in terms of the training experience.

Some of the aforementioned shortcomings of the Cunningham device are discussed at paragraphs [0006] through [0011] of appellant's specification. Of particular relevance to the claims on appeal is the shortcoming discussed at paragraphs [0009]-[0010]. Namely, for the device disclosed in Cunningham, the end effector (*i.e.,* catheter needle assembly (47)) is permanently coupled to the force-feedback system (*i.e.*, the receiver or shaft (44)).

As discussed in appellant's specification, it is not atypical for an end effector to be permanently coupled to its force-feedback system in a haptics device due to the difficulty of engineering a system that enables them to be decoupled. The inability to decouple the end effector from the force-feedback system is very undesirable, however, because to truly

mimic most "actual" systems (biological or otherwise), de-coupling is necessary. For example, in the case of an actual vascular-access procedure, a medical practitioner experiences force-feedback as she inserts a needle/catheter (*i.e.*, end effector) into a patient's arm. That is, the anatomy of the arm presents a resistance that is sensed by the practitioner. In the actual medical procedure, the needle/catheter is not "coupled" to the arm until so inserted by the practitioner.

In Cunningham's device, however, catheter needle assembly (47) is never dislodged from shaft (44); in other words, the catheter needle assembly is permanently coupled to the force-feedback system. A user does not, therefore, actually insert the catheter needle assembly (47), so there is no "coupling" and "decoupling" as during an actual vascular access procedure. In effect, in the Cunningham system, the simulation begins after the catheter/assembly has been "inserted" into a patient's arm. Cunningham therefore focuses on what's going on *after* insertion.

In applicant's claimed device, needle/catheter module (218) is not coupled to needle-stick module (226) until a user inserts module (218) therein during a simulated vascular-access procedure. And when the simulated procedure is over, the user withdraws needle/catheter module (218) from the needle-stick module. The user's interaction with the appellant's simulator more closely simulate a real vascular-access procedure than simulators in the prior art. This more realistic simulation is expected to result in a more useful training experience.

In any case, since there is no actual insertion of needle catheter assembly (47) into shaft (44), there is naturally no disclosure concerning a bevel at the end of a catheter or needle or any concern for the orientation of the (non-existing) bevel.

Furthermore, although Cunningham arguably discloses the use of a "pseudo skin," which would be belt (108) of skin traction mechanism (36), this pseudo skin does not include an opening for receiving the catheter and needle, as required by claim 1 on appeal. *See* FIG. 7 of Cunningham. As is clear from FIG. 3 of Cunningham, skin traction mechanism (36) is attached to case (32) of Cunningham's device, whereas catheter needle assembly (47) extends from within case (32) but not through the pseudo skin (belt 108) of the skin traction mechanism.

In summary, Cunningham does not disclose a bevel, Cunningham does not disclose a sensor for sensing the orientation of a bevel, and Cunningham does not disclose a pseudo skin having an opening for receiving a catheter and a needle.

Grayzel is directed to an introducing catheter and sheath having a diagonally tapered, beveled tip. Grayzel discloses that the catheter includes visible indicia to determine the orientation of the tip of the catheter and, hence, the bevel. The visible indicia enable a practitioner to re-orient the catheter once the entire tip is inserted (and the bevel is therefore no longer visible) so as to keep the bevel parallel to the wall of the vessel it is proceeding through.

The Examiner incorrectly characterized Grayzel as disclosing a needle/catheter *simulator*, which appeared to be his basis for incorporating the teachings of Grayzel into Cunningham: "it would have been obvious to combine the teachings of Cunningham and Grayzel as they're both needle/catheter simulators and analogous art." *See*, Official Action dated November 12, 2008 at page 2, paragraph 3, line 10.

Rosenberg discloses an apparatus for interfacing an elongated flexible object with an electrical system. In other words, Rosenberg discloses a simulator for simulating the manipulation of long flexible objects, such as catheters that are snaked through a patient's vascular system for performing angioplasty, *etc*.

In Rosenberg, like Cunningham, the focus appears to be manipulation of the elongated flexible object *after* insertion into an anatomy. In that regard, the Board's attention is directed to the Rosenberg's disclosure at col. 5, lines 1-29.

At that portion of the specification, Rosenberg discloses that the catheter, which is an actual medical catheter that should be purchased commercially for use with the system:

> "is modified such that the end of the tool (such as any cutting edges) are removed, leaving only the handle and shaft. The end of the catheter tool 108 is not required for the virtual reality simulation, and is removed to prevent any potential damage to persons or property."

In that passage, Rosenberg is explicitly stating that to the extent that the catheter has any sharp edges at its end (and a "bevel" for easing penetration through the skin would seem to qualify), they should be removed.

A few lines later, Rosenberg discloses that:

> "[t]he present invention is concerned with tracking the movement of the shaft portion 118 in three-dimensional space, where the movement has been constrained such that the shaft portion 118 has only two, three or four degrees of motion. This is a good simulation of the typical use of a catheter 108 in that once the catheter is inserted into a patient, it is limited to about two degrees of freedom. More particularly, the shaft 118 is constrained at some point along its length such that it can move with two degrees of freedom within the patient's body." (Emphasis added.)

In that passage, Rosenberg notes that the motion constraints imposed by his system are appropriate ("a good simulation") because once a catheter is inserted into a patient, the freedom of movement of the catheter is similarly limited.

These two passages aptly demonstrate that Rosenberg is not particularly concerned about the insertion portion of procedure.

Rosenberg does include a capability to monitor rotational (twisting) movement of the catheter or other elongated flexible object, but this appears to be to provide a capability to address vascular blockages, *etc*. *See*, *e.g.*, col. 13, line 67 through col. 14, line 2.

Rosenberg, like Cunningham, does not disclose or suggest incorporating a bevel or a means for monitoring the orientation of a bevel vis-à-vis a patient's skin during catheter/needle insertion. In fact, Rosenberg actually teaches away from using a beveled catheter in conjunction with his simulation system.

In view of the fact that Rosenberg teaches away from using a bevel and Cunningham does not address actual catheter insertion, these two references would seem to offer nothing whatsoever to support the rejection of the appellants claims under 35 USC §103(a). If Grayzel alone is insufficient to support a Section 103 rejection of appellants claims, which appellant believes to be the case, then the combination of these references are insufficient to support a prima facie case of obviousness of claim 1.

As a consequence, appellant respectfully requests that the Board reverse the Examiner's rejection of claim 1 over Cunningham, Rosenberg, and Grayzel. The rejection, over the same references, of claims 4-6, 8, and 10 should likewise be reversed since these claims are ultimately dependent on claim 1.

Claim 12 recites:

> pseudo skin;
> a force-feedback assembly, wherein said force-feedback assembly is disposed beneath and is at least partially covered by said pseudo skin; and
> an end effector, wherein said end effector passes through said pseudo skin to reversibly couple to said force-feedback assembly, and further wherein said end effector comprises a needle catheter module, wherein said needle-catheter module includes:
> a needle;
> a catheter, wherein said catheter receives said needle, and wherein an end of at least one of said needle or said catheter comprises a bevel; and
> a sensor, wherein said sensor senses an orientation of said bevel.

Claim 12 is allowable over Cunningham, Rosenberg, and Grayzel for at least the same reasons as claim 1. Namely, one skilled in the art would not find it obvious to incorporate a needle or catheter having a bevel and a sensor for sensing the orientation of the bevel into a vascular access simulator.

For these reasons, it is believed that the Examiner has not supported a prima facie case of obviousness of claim 12 under 35 USC §103(a). As a consequence, appellant respectfully requests that the Board reverse the Examiner's rejection of claim 12 over Cunningham, Rosenberg, and Grayzel. The rejection, over the same references, of claims 15-17 and 19 should likewise be reversed since these claims are ultimately dependent on claim 12.

CONCLUSION

The applicants have demonstrated that the logic underlying the Office's rejection is untenable, and, therefore, that the rejection is not sustainable. For this reason, the applicants respectfully request the Board of Appeals to reverse the decision of the Examiner as provided for in 37 C.F.R. 41.50(a).

Respectfully,
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Claims Appendix

1. (Previously Presented) An apparatus comprising:
a needle/catheter module, wherein the needle/catheter module comprises:
a needle;
a catheter, wherein said catheter receives said needle, and wherein at least one of said needle or said catheter comprise a bevel;
a sensor, wherein said sensor senses an orientation the bevel; and
pseudo skin, wherein said pseudo skin comprises an opening for receiving said needle and said catheter.

2. – 3. (Canceled)

4. (Previously Presented) The apparatus of claim 1 further comprising:
a receiver for receiving at least one of said needle and said catheter, wherein said receiver is disposed underneath said pseudo skin and covered by said pseudo skin.

5. (Original) The apparatus of claim 1 wherein said sensor is physically coupled to said needle.

6. (Previously Presented) The apparatus of claim 1 further comprising a data processing system that receives a signal that is indicative of said orientation of said bevel.

7. (Canceled)

8. (Previously Presented) The apparatus of claim 4 further comprising a housing, wherein said receiver is disposed within said housing, and wherein said pseudo skin is substantially co-planar with a surface of said housing.

9. (Canceled)

10. (Previously Presented) The apparatus of claim 1 further comprising:
a force-feedback assembly, wherein at least one of said needle and said catheter detachably couples to said force-feedback assembly.

11. (Canceled)

12. (Previously Presented) An apparatus comprising:

pseudo skin;

a force-feedback assembly, wherein said force-feedback assembly is disposed beneath and is at least partially covered by said pseudo skin; and

an end effector, wherein said end effector passes through said pseudo skin to reversibly couple to said force-feedback assembly, and further wherein said end effector comprises a needle catheter module, wherein said needle-catheter module includes:

a needle;

a catheter, wherein said catheter receives said needle, and wherein an end of at least one of said needle or said catheter comprises a bevel; and

a sensor, wherein said sensor senses an orientation of said bevel.

13. – 14. (Canceled)

15. (Original) The apparatus of claim 12 further comprising a data processing system, wherein said force-feedback assembly receives a control signal from said data processing system.

16. (Original) The apparatus of claim 15 wherein signals that are indicative of a position of said end effector are transmitted to said data processing system.

17. (Previously Presented) The apparatus of claim 12 further comprising a housing, wherein said force-feedback assembly is disposed within said housing and wherein said pseudo skin is substantially co-extensive with a surface of the housing.

18. (Canceled)

19. (Previously Presented) The apparatus of claim 12 further comprising a data processing system, wherein said data processing system receives a signal that is indicative of said orientation of said bevel.

20. – 28. (Canceled)

Evidence Appendix

There is no evidence submitted pursuant to 37 CFR §§ 1.130, 1.131, or1.132.

Related Proceedings Appendix

There are no related proceedings.